

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Application No.: 10/643,673
Filing Date: August 19, 2003
Applicant: Hyon et al.
Group Art Unit: 1711
Examiner: Susan Berman
Title: ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE
MOLDED ARTICLE FOR ARTIFICIAL JOINTS AND METHOD
OF PREPARING THE SAME
Attorney Docket: 1736-000001/REC

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. ☐ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated

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October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☒ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number
10/141,374

U.S. Filing Date
May 8, 2002

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☐ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☐ English translations are provided:

3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☒ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
10/141,374	May 8, 2002	Hyon et al.
10/643,674	August 19, 2003	Hyon et al.

V. THIS IDS IS BEING FILED UNDER

A. ☐ **37 C.F.R. § 1.97(b):** (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☒ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☒ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ 37 C.F.R. § 1.97(d):

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. ☒ A check in the amount of \$180.00 is enclosed for the above identified fee.

B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.


The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

Dated: 10 Jan 2006

By: 
David L. Suter
Reg. No. 30,692

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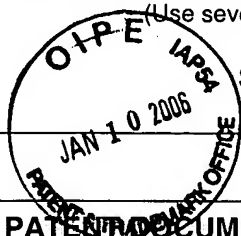
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FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 5



ATTORNEY DOCKET No.

SERIAL No.

1736-000001/REC

10/643,673

APPLICANT

Hyon et al.

FILING DATE

GROUP

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1711

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		4,902,460	02/20/1990	Yagi et al.		
2.		5,037,928	08/06/1991	Li et al.		
3.		5,478,906	12/26/1995	Howard, Jr.		
4.		5,508,319	04/16/1996	DeNicola, Jr. et al.		
5.		5,684,124	11/04/1997	Howard, Jr. et al.		
6.		5,824,411	10/20/1998	Shalaby et al.		
7.		2001/0049401	12/06/2001	Salovey et al.		
8.		6,372,814	04/16/2002	Sun et al.		
9.		2003/0158287	08/21/2003	Salovey et al.		
10.		6,664,308	12/16/2003	Sun et al.		
11.		2004/0208841	10/21/2004	Salovey et al.		
12.		6,818,020	11/16/2004	Sun et al.		
13.		2005/0059750	03/17/2005	Sun et al.		

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Ref. Desig.	Examiner's Initials	
1.		Appleby et al. "Post-Gamma Irradiation Cross-linking of Polyethylene Tape by Acetylene Treatment" Journal of Materials Science. Vol. 29 (1994) p. 227-231.
2.		Appleby et al. "Property Modification of Polyethylene Tapes by Acetylene-Sensitized Gamma Irradiation" Journal of Materials Science. Vol. 29 (1994) p 151-156.
3.		Bhateja et al. "Radiation-Induced Crystallinity Changes in Polyethylene Blends" Journal of Materials Science. Vol. 20 (1985) p. 2839-2845.
4.		Bhateja, S. "Radiation-Induced Crystallinity Changes in Pressure-Crystallized Ultrahigh Molecular Weight Polyethylene" J. Macromol. Sci. Phys. B22(1) (1983) p. 159-168.

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 2 of 5	ATTORNEY DOCKET NO.	SERIAL No.
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5.		Bowman, J. "The Processing and Properties of γ -Irradiated HDPE Granules" Intern. Polymer Processing III. (1988) p. 211-220.
6.		Chen et al. "Radiation-Induced Crosslinking: II. Effect on the Crystalline and Amorphous Densities of Polyethylene" Colloid Polym Sci. Vol. 269 (1991) p. 469-476.
7.		Chen et al. "Radiation-Induced Crosslinking: III. Effect on the Crystalline and Amorphous Density Fluctuations of Polyethylene" Colloid Polym Sci. Vol. 269 (1991) p. 353-363.
8.		Chu et al. "Some Structures and Properties of Very High Molecular Weight Linear Polyethylene" Bull. Inst. Chem. Res. Vol. 47, No. 3 (1969) p. 209-221.
9.		Dijkstra et al. "Cross-linking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation" Polymer. Vol. 30 (May 1989) p. 866-873.
10.		Dole et al. "Crystallinity and Crosslinking Efficiency in the Irradiation of Polyethylene" Radiat. Phys. Chem. Vol. 14 (1979) p. 711-720
11.		du Plessis et al. "The Improvement of Polyethylene Prostheses Through Radiation Crosslinking" Radiat. Phys. Chem. Vol. 9 (1977) p. 647-652.
12.		Ellwanger et al. "Very High Pressure Molding of Ultra High Molecular Weight Polyethylene (UHMWPE)" ANTEC. (1987) p. 572-574.
13.		Gauvin et al., "Investigation of the Radio Frequency Heating Process for UHMWPE" ANTEC. (1987) p. 575-578.
14.		Handlos, V. "Enhanced Crosslinking of Polyethylene" Radiat. Phys. Chem. Vol. 14 (1979) p. 721-728.
15.		Jahan et al. "Combined Chemical and Mechanical Effects on Free Radicals in UHMWPE Joints During Implantation" Journal of Biomedical Materials Research. Vol. 25 (1991) p. 1005-1017.
16.		Kanig, G. "Further Electron Microscope Observations on Polyethylene III. Smectic Intermediate State During Melting and Crystallization" Colloid Polym Sci. Vol. 269 (1991) p. 1118-1125.
17.		Kato et al. "Structural Changes and Melting Behavior of γ -Irradiated Polyethylene" Japanese Journal of Applied Physics. Vol. 20, No. 4. (April 1981) p. 691-697.
18.		Kitamaru et al. "A Commentary Remark on the Isothermal Crystallization of a Polyethylene Gel from the Stretched Molten State" Bull. Inst. Chem. Res. Vol. 46, No. 2 (1968) p. 97-106.

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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
19.		Kurth et al., "Effects of Radiation Sterilization on UHMW-Polyethylene" ANTEC. (1987) p. 1193-1197.
20.		Lin et al. "Review Structure and Plastic Deformation of Polyethylene" Journal of Materials Science. Vol. 29 (1994) p. 294-323.
21.		Matsubara et al. "The Wear Properties of High-Density Polyethylene Irradiated by Gamma Rays" Wear. Vol. 10 (1967) p. 214-222.
22.		Meyer, B. "Recent Developments in Radiation Sterilizable Plastics" ANTEC. (1987) p. 1190-1192
23.		Minkova et al. "Blends of Normal High Density and Ultra-High Molecular Weight Polyethylene, γ Irradiated at a Low Dose" Colloid Polym Sci. Vol. 268 (1990) p. 1018-1023.
24.		Minkova, L. "DSC of γ -Irradiated Ultra-High Molecular Weight Polyethylene and High Density Polyethylene of Normal Molecular Weight" Colloid Polym Sci. Vol. 266 (1988) p. 6-10.
25.		Nakayama et al. "Structure and Mechanical Properties of Ultra-High Molecular Weight Polyethylene Deformed Near Melting Temperature" Pure & Appl. Chem. Vol. 63, No. 12 (1991) p. 1793-1804.
26.		Oonishi et al. "Comparison of Wear of UHMWPE Sliding Against Metal and Alumina in Total Hip Prostheses - Wear Test and Clinical Results" 3rd World Biomaterials Congress, Transactions. (April 1988) p. 337.
27.		Oonishi et al. "Comparisons of Wear of UHMW Polyethylene Sliding Against Metal and Alumina in Total Hip Prostheses" Bioceramics. Vol. 1 (1989) p. 272-277.
28.		Oonishi et al. "Improvement of Polyethylene by Irradiation in Artificial Joints" Radiat. Phys. Chem. Vol. 39, No. 6 (1992) p. 495-504.
29.		Oonishi et al. "In Vivo and In Vitro Wear Behaviour on Weightbearing Surfaces of Polyethylene Sockets Improved by Irradiation in Total Hip Prostheses" Surface Modification Technologies V. (1992) p. 101-112.
30.		Oonishi et al. "SEM Observation on the Clinically Used Gamma-Irradiated Reinforced HDP Socket in Total Hip Replacement" Clinical Implant Materials, Advances in Biomaterials. Vol. 9 (1990) p. 379-384.

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Ref. Desig.	Examiner's Initials	
31.		Oonishi et al. "Wear Resistance of Gamma-Ray Irradiated U.H.M.W. Polyethylene Socket in Total Hip Prosthesis - Wear Test and Long Term Clinical Results" MRS Int'l. Mtg. on Adv. Mats. Vol. 1 (1989) p. 351-356.
32.		Oonishi et al. "Wear Resistance of Gamma-Ray Irradiated UHMWPE Socket in Total Hip Prostheses - Wear Test and Long Term Clinical Results" 3rd World Biomaterials Congress, Transactions. (April 1988) p. 588.
33.		Patel, G. "Acceleration of Radiation-Induced Crosslinking in Polyethylene by Diacetylenes" Radiat. Phys. Chem. Vol. 14 (1979) p. 729-735.
34.		Rimnac et al. "Chemical and Mechanical Degradation of UHMWPE: Report of the Development of an In Vitro Test" Journal of Applied Biomaterials. Vol. 5 (1994) p. 17-21.
35.		Rose et al. "Exploratory Investigations on the Structure Dependence of the Wear Resistance of Polyethylene" Wear. Vol. 77 (1982) p. 89-104
36.		Salovey et al. "Irradiation of Ultra High Molecular Weight Polyethylene" Polymer Preprints. Vol. 26, No. 1 (1985) p. 118-119
37.		Salovey, R. "On the Morphology of Crosslinking Polymers" Polymer Letters. Vol. 2 (1964) p. 833-834.
38.		Sandford et al. "Shelf Life Prediction of Radiation Sterilized Medical Devices" ANTEC (1987) p. 1201-1204.
39.		Sawatari et al. "Crosslinking Effect of Ultrahigh Molecular Weight Polyethylene-Low Molecular Weight Polyethylene Blend Films Produced by Gelation/Crystallization From Solutions" Colloid Polym Sci. Vol. 269, No. 8 (1991) p. 795-806.
40.		Shen et al. "The Friction and Wear Behavior of Irradiated Very High Molecular Weight Polyethylene" Wear. Vol. 30 (1974) p. 349-364.
41.		Streicher, R. "Change in Properties of High Molecular Weight Polyethylenes After Ionizing Irradiation for Sterilization and Modification" Third International Conference on Radiation Processing for Plastics and Rubber (November 1987) (9 pages).
42.		Streicher, R. "Influence of Ionizing Irradiation in Air and Nitrogen for Sterilization of Surgical Grade Polyethylene for Implants" Radiat. Phys. Chem. Vol. 31, Nos. 4-6 (1988) p. 693-698.
43.		Streicher, R. "Investigation on Sterilization and Modification of High Molecular Weight Polyethylenes by Ionizing Irradiation" Reprint from beta-gamma 1/89 p. 34-43

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44.		Streicher, R. "Ionizing Irradiation for Sterilization and Modification of High Molecular Weight Polyethylenes" <i>Plastics and Rubber Processing and Applications</i> . Vol. 10, (1988) p. 221-229.
45.		Waldman et al. "Compressive Stress Relaxation Behavior of Irradiated Ultra-High Molecular Weight Polyethylene at 37°C" <i>Journal of Applied Biomaterials</i> . Vol. 5 (1994) p. 333-338.
46.		Wang et al. "Melting of Ultrahigh Molecular Weight Polyethylene" <i>Journal of Applied Polymer Science</i> . Vol. 34 (1987) p. 593-599.
47.		Ward, I. "New Developments in the Production of High Modulus and High Strength Flexible Polymers" <i>Progr Colloid Polym Sci</i> . Vol. 92 (1993) p. 103-110.
48.		Williams, J. "Radiation Stability of Polypropylene" <i>ANTEC</i> . (1987) p. 1198-1200.
49.		Wong et al. "Molecular Deformation Processes in Gel-Spun Polyethylene Fibres" <i>Journal of Materials Science</i> . Vol. 29 (1994) p. 520-526.
50.		Zhao et al. "Effect of Irradiation on Crystallinity and Mechanical Properties of Ultrahigh Molecular Weight Polyethylene" <i>Journal of Applied Polymer Science</i> . Vol. 50 (1993) p. 1797-1801.
51.		Zoepfl et al. "Differential Scanning Calorimetry Studies of Irradiated Polyethylene: I. Melting Temperatures and Fusion Endotherms" <i>Journal of Polymer Science: Polymer Chemistry Edition</i> . Vol. 22 (1984) p. 2017-2032.
52.		Zoepfl et al. "Differential Scanning Calorimetry Studies of Irradated Polyethylene: II. The Effect of Oxygen" <i>Journal of Polymer Science: Polymer Chemistry Edition</i> . Vol. 22 (1984) p. 2033-2045.

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